UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL	
INDUSTRY AVERAGE)
WHOLESALE PRICE)
LITIGATION)
THIS DOCUMENT RELATES TO:) MDL No. 1456
United States ex rel. Linnette Sun) Master File No: 01:cv-12257-PBS
and Greg Hamilton, Relators) wiaster the No. 01.ev-12237-1 bs
v.) Sub-Category Case No. 06-11337
Baxter Healthcare Corporation)
Case No. 08-cv-11200-PBS)
) Judge Patti B. Saris
United States of America ex rel.	
Ven-A-Care of the Florida Keys, Inc.)
v.)
Baxter Healthcare Corporation and)
Baxter International, Inc.)
Case No. 10-cv-11186-PBS)
)

RELATOR VEN-A-CARE'S PRE-HEARING BRIEF <u>AND PRESENTATION OF FACTS</u>

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INDEX OF EXHIBITS TO Relator Ven-A-Care's Pre-Hearing Brief and Presentation of Facts

Exhibit #	Description	Document #, if appropriate
1	Original Sealed Miami Complaint filed in the Southern District of Florida on June 25, 1995 (Redacted for Baxter)	
	Second Amended Sealed Miami Complaint filed in the Southern District of Florida on August 13, 1997 (Redacted for Baxter)	See Document 8224-1 Notice of Filing Pleading from Transferor Court File
2	Third Amended Sealed Miami Complaint filed in the Southern District of Florida on December 9, 1999 (Redacted for Baxter)	
	Fourth Amended Sealed Miami Complaint filed in the Southern District of Florida on December 11, 2002 (Redacted for Baxter)	See Document 8205-3 Declaration of James J. Breen submitting exhibits, et al.
3	Deposition of Baxter 30-b-6 witness - Michael Bradley taken on January 28, 2013 (with exhibits)	
4	Deposition of Greg Hamilton taken on January 29, 2013 (with exhibits)	
5	Texas Settlement Agreement dated June 6, 2006	
6	California Settlement Agreement dated December 9, 2008	
	Ven-A-Care and Baxter Settlement Agreement (including the State of Florida) Filed October 7, 2011	Document 7831-1 Document 26-1 Exhibit A to John Lockwood Declaration
	Sun Hamilton sealed complaint filed in US District Court, District of Colorado on April 19, 2005	08-cv-11200-PBS Document 57-2

Pursuant to the Court's direction, Ven-A-Care of the Florida Keys, Inc., hereby submits its Pre-Hearing Brief and Presentation of Facts.¹ At this time, Ven-A-Care believes that the pertinent facts are not genuinely in dispute. However, Ven-A-Care reserves the right to present additional evidence at the hearing now scheduled to begin April 16, 2013, as well as to controvert evidence presented by other parties in this matter.

I. Summary of Ven-A-Care's Position

The Sun/Hamilton Rule 60(b)(6) motion places Ven-A-Care in the unusual position of defending its standing as an FCA qui tam relator after having pursued its 1995 action against Baxter to a successful settlement resulting in a final judgment and dismissal nearly two years ago.

At the telephone status conference held March 18, 2013, the Court raised the question whether Sun/Hamilton need only make a threshold showing of facts supporting their first-to-file, subject-matter jurisdiction position. Here, the issue is not presented at the usual preliminary juncture where a provisional finding of subject-matter jurisdiction allows the matter to move forward and the facts to be developed subject to reconsideration of the court's initial determination. The Court has already concluded that Ven-A-Care's settlement extended to Advate, and Sun/Hamilton now seek to invalidate the settlement by contending that the Court lacked subject-matter jurisdiction over Advate in Ven-A-Care's action.

Because its action has been finally adjudicated and dismissed with prejudice, Ven-A-Care need only show "an arguable basis" that the Court's subject-matter jurisdiction extended to

¹ Pursuant to the Court's instructions, Ven-A-Care has limited its arguments and assertions of fact to those pertinent to the first-to-file, subject matter jurisdiction issue.

Advate in its earlier filed action. See *Baella-Silva v. Hulsey*, 454 F.3d 5, 9-10 (1st Cir. P.R. 2006) (the record need show only "an arguable basis" for subject-matter jurisdiction in order for the court's settlement judgment to be enforceable); *Quincy V, LLC v. Herman*, 652 F.3d 116, 121 (1st Cir. Mass. 2011) (Citing *Baella-Silva* as to the court's ancillary jurisdiction to enforce a settlement.).

Sun/Hamilton must do much more than make a preliminary showing of evidence supporting their assertion that they were first to file as to Advate. Instead, Sun and Hamilton must present sufficient compelling evidence for the Court to make a final determination that there is not even an arguable basis to conclude that it possessed subject-matter jurisdiction over Advate in Ven-A-Care's action. Fafel v. DiPaola, 399 F.3d 403 (1st Cir. 2005). Ven-A-Care specifically identified the earlier and therapeutically equivalent Baxter recombinant product known as Recombinate in its earlier filed action. While Advate may have been an improved version of that recombinant product, both versions continued to be manufactured by the same Baxter division and priced and marketed by the same Baxter personnel to the same healthcare providers, for administration in the same manner to the same patients, for treatment of the same condition. Moreover, Recombinate and Advate were both the kind of infusion biological product that Ven-A-Care's 1995 FCA qui tam action focused on, and about which Ven-A-Care was especially knowledgeable. It is virtually incomprehensible that a government investigation of the allegations of Ven-A-Care's December 11, 2002 Fourth Amended Complaint would not have encompassed Advate, introduced mere months after Ven-A-Care's filing and referenced in Baxter's pricing and marketing documents along with Recombinate because Baxter was trying to convert customers to the new, follow-on recombinant product.

Sun and Hamilton cannot meet their burden of demonstrating that no arguable basis existed to support subject matter jurisdiction in Ven-A-Care's finally adjudicated action.

II. Facts Presented in Advance of Evidentiary Hearing Set for April 16, 2013

1. Advate and Recombinate are both anti-hemophilia blood factor VIII recombinants

that the same Baxter personnel priced, marketed, and sold in the same manner to

the same customers, for administration to the same patients, to treat the same

illness.

The uncontroverted testimony of Baxter's corporate representative, Michael Bradley, is that Advate and Recombinate are both blood factor VIII replacement therapies known as "recombinants" that were manufactured by the same Baxter division, priced in the same manner, by the same Baxter personnel and then marketed to the same health care providers, for administration in the same manner to the same patients, for treatment of the same medical condition. (See Bradley (1/28/13) 100:20-100:24; 106:20-112:15; 114:1-114:6; 127:23-128:18). These two recombinant blood factor VIII products also consist of the same active biological ingredients and are manufactured in the same manner from the exact same cell line. *Id.* at 89:13 – 92:24. The only difference between the two is that, with Advate, there is no exposure to human or animal proteins in the production process. *Id.* This absence of protein was intended to distinguish Advate from other blood factor VIII recombinants. Baxter hoped to convert patients from Recombinate to Advate and charge a premium for Advate in relation to Recombinate. (See Bradley 125:4 - 127:3). Despite this initial hope, Baxter set both market pricing and

published pricing for Advate within 5-7% of Recombinate; in a remarkably similar manner to that of Recombinate. (See Bradley 103:1 - 105:22).

The resulting reimbursement spreads for Advate and Recombinate were naturally also similar and not even the purported new relator, Greg Hamilton, disputes this fact. (See Hamilton (1/29/13) 89:4 - 89:20.) In fact, when Baxter decreased the market price of Advate not long after its launch, Baxter also chose to lower the published pricing of Advate to an even greater degree. (See Bradley 103:1 – 105:22). Baxter's pricing revision was instituted at that early date to decrease any reimbursement spread on Advate in relation to other blood factor VIII recombinants, such as Recombinate, and it further conformed the pricing of Advate to Recombinate. (See Bradley 103:1 – 105:22; 127:4 – 127:20). These changes all occurred before Sun/Hamilton filed their initial Complaint. (See docket entry 57-2 - Sun/Hamilton original Complaint filed April 19, 2005). Even Hamilton had to agree that Baxter used the same pricing tactics and schemes for both Recombinate and Advate. (See Hamilton 90:4 - 91:2.)

2. Ven-A-Care was the first relator to file an FCA *qui tam* action alleging that

Baxter defrauded the Medicare and Medicaid Programs through a fraudulent drug

price reporting scheme and, in addition to other related conduct, specifically

alleged and informed the government that the scheme included the reporting of

false WACs to FDB, knowing they would be used to determine false inflated

AWPs that were in turn reported to state Medicaid Programs.

As a specialty infusion/homecare pharmacy, Ven-A-Care was part of the market segment to which Baxter marketed its biological products; *i.e.*, specialty infusion/homecare pharmacies

and the specialty distributors that serviced them. Accordingly, Ven-A-Care had access to actual market pricing that was not available to the public or to the Medicare and Medicaid programs and was much lower than published pricing. (See Lockwood Declaration ¶ 4.) As a small specialty pharmacy, Ven-A-Care did not have volume purchasing power or the ability to negotiate the lowest prices within its market; however, it was uniquely situated to know the upper range of the true market prices, which were dramatically lower than the prices published for outsiders to see. (See Ven-A-Care's Fourth Amended Complaint at p. 94). Ven-A-Care was thus able to evaluate the truthfulness of many manufacturers' public price representations across a broad spectrum of drug and biological products. This knowledge formed the foundation of Ven-A-Care's allegations and disclosures to the government.

Ven-A-Care's industry insider knowledge also extended to the manner in which drug manufacturers caused and influenced the publicly available pricing for their drug and biological products in compendia such as First Data Bank ("FDB") that are widely relied on by state Medicaid programs and other government insurers in setting reimbursement amounts. (See Lockwood Declaration $\P 11 - 20$ and 23 - 24). Ven-A-Care's industry insight enabled it to allege specifically the various schemes Baxter and other drug manufacturers used to cause reporting compendia to publish false pricing for their products, including the reporting of inflated WAC or wholesale net pricing to cause the publication of inflated AWPs. (See Lockwood Declaration $\P 14 - 17$ and 20).

Ven-A-Care used its extensive industry insider knowledge as a customer or potential customer of many manufacturers to develop and launch the first of what would become known as the "AWP cases."

Ven-A-Care "blew the whistle" on Baxter's conduct a full ten years before Sun or Hamilton informed the government of some of the details about one product involved in the fraudulent scheme that was already being investigated.

The broad scope of Ven-A-Care's knowledge, and the number of manufacturers and pharmaceutical products encompassed, necessitated that VAC plead examples of specific products about which the defendants were reporting false price information and then extensively support its allegations by providing the government with the key piece of knowledge it had previously lacked: continual access to actual market prices for all of the drug and biological products marketed by the defendants in comparison with reported prices. (See Lockwood Declaration ¶¶ 11 and 19; see also Jones Declaration.)

Ven-A-Care's allegations and disclosures to the government (and to the states at the request of the United States Department of Justice) included detailed explanations of how the defendants reported false inflated prices and costs to FDB, knowing that they would be used to determine false inflated AWPs. Ven-A-Care was careful to allege and otherwise educate the government that drug manufacturers identified the prices and costs that they reported to FDB in a number of ways, such as WAC, List, Direct, and Wholesale Net and further explained that these reports falsely represented inflated prices as prices charged at the wholesale level. (See Lockwood Declaration ¶¶ 11 − 13, 20 and 23 - 24).

Ven-A-Care was also very specific in alleging and informing the government that a significant portion of drug sales did not flow through the major wholesalers. (Lockwood Declaration ¶ 20). This was particularly true as to biological products. *Id.* Ven-A-Care specifically alleged that entities known as FFF (also known as FFF Enterprises), Oncology

Therapeutic Network (OTN), Florida Infusion, Alternate Site Distributors (ASD), National Specialty Services (NSS), and Oncology Supply were some of Ven-A-Care's specialty suppliers of biological products who bought and sold Baxter products as prices lower than the products' respective published prices. *Id.* Ven-A-Care also provided pricing information to the government from wholesaler distributors such as Bio Med Plus. Virtually all of these same entities were later noted by Sun/Hamilton in their subsequent Complaint as customers of Baxter's that received prices lower than Baxter's published prices. (See Sun/Hamilton 2005 Complaint ¶ 28). Ven-A-Care provided the government with FFF's and Bio Med Plus's marketing materials or low market pricing for specialty biological products such as blood factor recombinants Recombinate and Advate. (See Lockwood Declaration ¶ 11). Ven-A-Care also shared other specialty suppliers' pricing with the United States and the states. *Id*.

As mentioned briefly above, Ven-A-Care also specifically alleged and informed the government that Baxter's fraudulent scheme included making or causing the making of reports of price and cost information to FDB that Baxter knew would be used to determine AWPs through the practice of FDB adding a percentage and/or applying what was also known as a "mark-up". (See Lockwood Declaration ¶ 14 – 15 and 23 - 24; see also ¶ 161(b) of Ven-A-Care's Fourth Amended Complaint filed Dec. 11, 2002). Ven-A-Care alleged the resulting inflated, false AWPs would be published by FDB to the state Medicaid Programs and would cause such programs to pay inflated drug reimbursements far beyond any reasonable estimation of acquisition cost. (See Lockwood Declaration ¶ 6, 9, 12, 14 - 20). Ven-A-Care further alleged and otherwise informed the government that such false reports to FDB were in the form of a variety of price information such as WAC, Wholesale Net and List Prices as well as through

the aforementioned application of a "mark-up" to such prices to publish, in turn, an inflated AWP. *Id*.

Ven-A-Care also specifically named the Baxter blood factor VIII recombinant marketed under the name "Recombinate" as one of several drugs that exemplified Baxter's product-linewide false pricing schemes. (See Lockwood Declaration ¶ 18; see also Ven-A-Care's Fourth Amended Complaint at page 6 of Exhibit 2 filed 12/11/02 (Docket Entry # 8205-3)). Ven-A-Care made these allegations well before Sun or Hamilton commenced their later filed qui tam action and the government instituted its investigation accordingly as is addressed below. Ven-A-Care even went so far as to specifically enumerate the spread attributable to the recombinant blood factor VIII known as Recombinate at 41%. *Id*.

To assist with the government's investigation of its allegations, Ven-A-Care made its industry insider pricing information available to the government on an ongoing and continuous basis and repeatedly incorporated this pricing information into presentations for the government. (See Lockwood Declaration ¶ 11- 13 and 16 - 21). Ven-A-Care's willingness to share its extensive access to industry insider pricing and other information was a key weapon that enabled the states and the federal government to recover in the state and federal AWP cases. By way of example, this Court denied motions to dismiss the action by the New York counties after noting that they had acquired access to Ven-A-Care's pricing information and, accordingly, could plead with the requisite particularity. (See April 2, 2007 Order issued by this Court in this MDL No. 1456). Ven-A-Care presented this pricing information in conjunction with detailed explanations of the mechanisms and techniques by which drug company Defendants, including specifically Baxter, would report or cause to be reported false and inflated published prices such as AWP as

well as the lower price points of WAC, Direct, WHN, wholesale net, and list. (See Lockwood Declaration ¶ 11- 13 and 16 - 21).

In addition to making these presentations to various government investigators responsible for pursuing and prosecuting FCA and state *qui tam* claims, Ven-A-Care also participated in Congressional hearings that led to meaningful, substantive changes in both Medicare and Medicaid drug reimbursement methodologies. (See Lockwood Declaration ¶ 21).

3. A reasonable government investigation of Ven-A-Care's allegations would have encompassed Advate.

The Department of Justice opted to keep Ven-A-Care's FCA qui tam action against

Baxter under seal for 15 years while the government investigated Ven-A-Care's allegations. DOJ

opted to coordinate its investigation with those being conducted by the attorneys general of

various states, such as Texas and California, and asked Ven-A-Care to assist with the joint
investigation. Ven-A-Care's efforts in this regard included providing numerous briefings and
presentations to state attorneys generals' offices that were attended by US DOJ representatives.

(See Lockwood Declaration ¶¶ 19 – 21). Ven-A-Care's participation in the joint investigations
continued at DOJ's request after the filing of the Fourth Amended Complaint in December 2002,
and Ven-A-Care was specifically asked by DOJ to work with the Texas Attorney General's
representatives to come up with a list of all of Baxter's drug and biological products that were
involved in the fraudulent scheme Ven-A-Care had alleged. (See Lockwood Declaration ¶ 25).

Ven-A-Care principals Dr. Lockwood and Mark Jones assisted the Texas personnel in creating a
spreadsheet listing these products, along with a rough estimate of spreads and potential impact

upon Medicaid, which was conveyed to DOJ in August 2004, several months before the commencement of the Sun/Hamilton action. *Id.* Since Baxter was marketing its recombinants under the names Recombinate and Advate by August 2004, both were included in the joint DOJ/Texas investigation and appear on the spreadsheet. *Id.*

4. The scope of prior Ven-A-Care state settlements rightfully included claims

regarding all Baxter drugs, including Advate, because all such drugs were part of
the scheme pled by Ven-A-Care.

Ven-A-Care settled each of its four state and federal qui tam actions against Baxter wherein it alleged the fraudulent scheme described above. The settlements of its Texas, California and Florida actions in 2006, 2009 and 2011, respectively, all encompassed all of Baxter's recombinant products and the three states actually joined in the settlements as parties with full authority to provide releases on behalf of the states. The Florida Settlement occurred as part of the settlement of Ven-A-Care's US FCA *qui tam* action against Baxter in which the US DOJ declined to intervene or join as a party to the settlement. Each of Ven-A-Care's settlements with Baxter defines the "Covered Conduct" forming the basis of the settlement and release to include the fraudulent scheme pleaded by Ven-A-Care described above. (See Lockwood Declaration ¶ 8).

Nothing about Advate would cause it to fall outside the scope of Ven-A-Care's earlier filed FCA qui tam action against Baxter regarding recombinants, for first-to-file purposes.

III. Legal Argument

1. Sun/Hamilton bear a heavy burden in collaterally attacking a final judgment.

Sun/Hamilton seek to set aside the final judgment entered nearly two years ago as a result of the settlement between Ven-A-Care and Baxter. To obtain this extraordinary relief, Sun/Hamilton must establish that this Court lacked subject-matter jurisdiction in Ven-A-Care's 1995 FCA qui tam action over the one remaining drug at issue, Advate, and that Sun/Hamilton was first-to-file a qui tam case encompassing Advate under the False Claims Act. When a judgment is collaterally attacked, "'competing policies are at stake,' namely the 'observation of limits on federal jurisdiction" in opposition to the "need for judgments that are final." Fafel v. DiPaola, 399 F.3d 403, 410 (1st Cir. 2005); quoting, Kan. City S. Ry. v. Great Lakes Carbon Corp., 624 F.2d 822, 826 (8th Cir. 1980) (en banc); see also Hodge v. Hodge, 621 F.2d 590, 592, 17 V.I. 623 (3d Cir. 1980) ("Unless more than the private interests of the litigants is at stake, even the issue of subject-matter jurisdiction must at some point be laid to rest."); Lubben v. Selective Service System Local Board, 453 F.2d 645, 650 (1st Cir. 1972) (noting a need for "the certainty which allows controversies to be deemed judicially concluded"). Accordingly, a final adjudication of an action should not be disturbed due to assertions of lack of subject-matter jurisdiction in a Rule 60 proceeding if there is an "arguable basis" to conclude that the Court possessed subject-matter jurisdiction.

Given the strong interest in preserving the finality of adjudications, Ven-A-Care urges that Sun/Hamilton must do much more than merely make a preliminary showing they were first-to-file as to Advate. Instead, Sun/Hamilton must present evidence which compels a final

determination that not even an "arguable basis" exists to conclude this Court possessed subject-matter jurisdiction over Advate in Ven-A-Care's action. As explained below, the law and the facts reveal much more than an "arguable basis" for such subject-matter jurisdiction in Ven-A-Care's case as to Advate.

2. Sun/Hamilton's Advate claim was precluded under 31 U.S.C. § 3730(b)(5) by Ven-A-Care's earlier–filed action.

31 U.S.C.A. § 3730 (b) (5) precludes a second-in-time relator from bringing a qui tam action "based on the facts underlying" a pending FCA qui tam action. Specifically, the First Circuit has found that the first-to-file bar contained in 31 U.S.C § 3730 (b) (5) restricts the Court's subject-matter jurisdiction such that the Court cannot even entertain a second in time *qui tam* action alleging the same fraudulent scheme as an earlier pending action "even if that claim incorporates somewhat different details." *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 20 and 32 (1st Cir. 2009), quoting with approval, *United States ex rel. LaCorte v. SmithKline Beecham Clinical Laboratories, Inc.*, 149 F.3d 227, 232-233 (3rd Cir. 1998). The First Circuit further emphasized "a goal behind the first-to-file rule' is to provide incentives to relators to 'promptly alert the government to the essential facts of a fraudulent scheme." *Id.* at 32. "[A] relator who merely adds details to a previously exposed fraud does not help 'reduce fraud or return funds to the federal fisc,' because 'once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds."" *United States ex rel Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 378 (5th Cir. 2009).

Sun and Hamilton's qui tam action regarding Baxter's blood factor VIII recombinant

Advate is at most merely an added "detail." Ven-A-Care had previously alleged a multi-faceted

drug pricing fraud scheme as to all of Baxter's drugs and biological products, specifically including and naming another Baxter blood factor VIII recombinant, Recombinate. This fraud scheme encompassed all aspects and price points at issue, including the false reporting of WAC pricing that did not reflect prices actually paid by the wholesaler/distributor classes of trade, and the reporting of false list or WAC or wholesale net prices, which enabled the addition by First Data Bank of an incremental % or "mark-up" leading to an even higher-priced and false, misleading AWP. Advate was conceived as a follow-on product, marketed contemporaneously with Recombinate to the same health care providers for the same purposes, and promoted as carrying a reduced risk of certain complications for certain patients.

Certainly, Ven-A-Care's long-standing fraud scheme allegations, dating back to 1995, should have alerted the government to any similar pricing fraud as to Advate, particularly in light of Ven-A-Care's many presentations, explanations of the schemes employed by Baxter and other drug company defendants, and disclosures of pricing information to the U.S. DOJ, the state AGs, Congress and the OIG, to name a few. In fact, the government did actually include Advate in aspects of its investigation, as cited above. The scope of the investigation encompassing Advate is understandable because Advate was manufactured, marketed, priced, and sold by the same division of Baxter and the same Baxter personnel to the same Baxter customers. These similarities are important factors to consider, as this Court set forth in another Ven-A-Care case in reaching the conclusion that one Ven-A-Care case did not bar a later Ven-A-Care case wherein the Erythromycin drugs at issue in the later case were manufactured, marketed, priced and sold by a different Abbott division and different personnel to different

customers with different pricing mechanisms and a different scheme. *United States ex rel. Ven- A-Care v. Abbott Labs, Inc.*, 2008 WL 2778808 (D. Mass. July 15, 2008).

Finally, the latest Ven-A-Care Amended Complaint against Baxter was filed in 2002. Hamilton's allegations center upon the treatment by First Data Bank of Baxter pricing which began in 2001 and affected all Baxter biologicals. Not only did Hamilton fail to timely alert the government to his purportedly new allegations (waiting idly for some four years without any effort to notify the United States), but when Baxter launched Advate in 2003, Baxter engaged in the same false price reporting as it had in reporting pricing for Recombinate and all other Baxter biological products. Hence, while Advate was launched after Ven-A-Care's last amendment in 2002, Ven-A-Care had already pleaded the full spectrum of the pricing schemes Baxter applied in reporting pricing for recombinants, including Advate. In a remarkably similar factual scenario, and in a case relied upon by the First Circuit in *Duxbury*, the Third Circuit held the original relators' failure to specifically name one blood test later named by a second relator, while the original relators named other blood tests, was "of no significance" because the original relators alleged the same essential facts and the second relator did not describe a separate scheme as to the newly-named blood test. United States ex rel. LaCorte v. SmithKline Beecham Clinical Laboratories, Inc., 149 F.3d 227, 237 (3rd Cir. 1998). Just as in LaCorte, the second relators here, Sun and Hamilton, cannot even seriously contend they alleged a fraudulent scheme that was different for Advate as compared to the other Baxter products, including Recombinate.

Therefore, Sun/Hamilton cannot meet their burden of establishing subject-matter jurisdiction in their case because they were not first-to-file an FCA qui tam action alleging a drug pricing scheme on the part of Baxter regarding the pricing of its drug and biological products,

including Advate. Further, they cannot satisfy the much more demanding requirement of establishing that no "arguable basis" exists to find jurisdiction in the Ven-A-Care case.

IV. <u>Prayer</u>

Ven-A-Care urges that the extraordinary relief Sun/Hamilton seek through their Motion under Rule 60(b) be in all respects denied so that the final judgment entered in the Ven-A-Care matter (Case No. 10-cv-11186-PBS) will not be set aside. In the alternative, if this Court concludes that Baxter, Ven-A-Care and/or the United States lacked the authority to settle the Advate claims because they were first filed under the FCA by Sun or Hamilton, then Ven-A-Care requests that its Settlement Agreement with Baxter be interpreted and construed as not applying to them.²

Respectfully submitted,

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² As Ven-A-Care has argued previously, Ven-A-Care specifically agreed to only settle claims on behalf of the United States that it was authorized by law to settle as an FCA qui tam relator and, in addition, the settlement agreement contains a severability clause.

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For Ven-A-Care of the Florida Keys, Inc.

CERTIFICATE OF SERVICE

I hereby certify that I have this 9th day of April, 2013 caused an electronic copy of the above PRE-HEARING BRIEF AND PRESENTATION OF FACTS to be served on all counsel of record via email as well as through electronic service by sending a copy to Lexis Nexis File and Serve for posting and notification to all parties.

/s/ Jarrett Anderson